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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,092	01/11/2002	Jolyon Jesty	0974/1F828-US1	6018
7278	7590	11/18/2005	EXAMINER	
DARBY & DARBY P.C. P. O. BOX 5257 NEW YORK, NY 10150-5257			VENC1, DAVID J	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 11/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/031,092		JESTY ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	David J. Venci		1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on August 19, 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 11-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 11-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>08/19/05</u> | 6) <input type="checkbox"/> Other: _____  |

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### DETAILED ACTION

Examiner acknowledges Applicants' reply, filed August 19, 2005, which amended claims 1, 4 and 13.

Currently, claims 1-8 and 11-20 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Claim Rejections - 35 USC § 112***

Claims 1-8 and 11-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1 and 13, the recitation of "a property" is indefinite. What physical structure(s) and/or procedural step(s) are required of "said product" to acquire "a property" is/are not clear.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted step(s) is/are the step(s) required for "assaying the activation state of said platelets". According to Applicants' specification, platelet "activation state" may require determination of: (1) the level of prothrombinase activity associated with a platelet; or (2) the level of thrombin which is produced as a result of the prothrombinase catalysis (see e.g., p. 6, lines 14-16). However, claim 1 does not appear to recite either (1) or (2) above.

In claim 1, the recitation of the adverb "thereby" is indefinite. The identity of object(s) (e.g., verbs, adjectives, adverbs and/or prepositions) modified by "thereby" is/are not clear.

***Claim Rejections - 35 USC § 102***

Claims 1-4, 7-8, 11-14 and 16-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Henriksen, 22 METHODS ENZYMOL. 312 (1993).

Henriksen describes a method for assaying activation state of platelets comprising: reacting a mixture comprising said platelets (see p. 316, line 9, "plasma"), a prothrombin-converting enzyme (see p. 316, line 10, "taipan venom reagent"), a substrate of said prothrombin-converting enzyme (see p. 316, line 19, "prothrombin") to produce a product (see p. 315, third full paragraph, line 6, "fibrinogen clot formation"); and assaying the product (see p. 315, third full paragraph, line 6, "end point for this assay is fibrinogen clot formation"), wherein said product does not activate platelets (see Table I).

With respect to claims 8, 11-12, 14 and 17-18, Henriksen describes a tosyl-Gly-Pro-Arg-p-nitroanilide chromogenic peptide (see p. 321, first full paragraph).

***Claim Rejections - 35 USC § 103***

Claims 5-6 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henriksen, 22 METHODS ENZYMOL. 312 (1993), in view of Harris & Kozlowski (US 6,541,543).

Henriksen describes a method for assaying prothrombin activation as substantially described, *supra*, and incorporated herein.

Henriksen does not teach a prothrombin chemically derivatized with an acetyl group donated by sulfo-N-succinimidyl acetate.

However, Harris & Kozlowski teach the use of sulfo-N-succinimidyl acetate (see col. 15, lines 60-61) for derivatizing proteins. Therefore, it would have been obvious for a person of ordinary skill in the art to perform the method of Henriksen et al. and Hemker & Wagenvoort with prothrombin chemically derivatized with sulfo-N-succinimidyl acetate because Harris & Kozlowski discovered that sulfo-N-succinimidyl acetate increases protein solubility and decreases immunogenicity (see col. 4, lines 61-65).

***Response to Arguments***

In prior Office Action, claims 13-14 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite the recitation of "an assay of said product". Claim 14 was rejected because the identity of the compounds and/or instruments encompassing each of the recited Markush members was not clear. Applicants' argumentation is fully persuasive and sufficient to overcome these rejections. Accordingly, these rejections are withdrawn.

In prior Office Action, claims 1-8 and 11-20 were rejected under 35 U.S.C. 103(a) as being unpatentable over various combinations of teachings of Henriksen et al., 66 J. CLIN. INVEST. 934 (1980), Hemker & Wagenvoord (US 5,266,462), Harris & Kozlowski (US 6,541,543), and Lottenberg et al., 80 METHODS ENZYMOL. 341 (1981). In response, Applicants amend claim 1 to add, *inter alia*, the step of "reacting" a mixture comprising platelets, a prothrombin-converting enzyme and a substrate. Applicants' amendment and related argumentation are fully persuasive and sufficient to overcome these rejections. Accordingly, these rejections are withdrawn.

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**Conclusion**

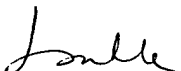
No claims are allowed at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

David J Venci  
Examiner  
Art Unit 1641

djv

  
LONG V. LE  
SUPERVISORY PATENT EXAMINER  
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11/10/05